

# EXHIBIT B

United States Code Annotated  
Title 42. The Public Health and Welfare  
Chapter 6A. Public Health Service (Refs & Annos)  
Subchapter XXVIII. Health Information Technology and Quality  
Part A. Promotion of Health Information Technology

42 U.S.C.A. § 300jj-11

§ 300jj-11. Office of the National Coordinator for Health Information Technology

Effective: December 13, 2016

[Currentness](#)

**(a) Establishment**

There is established within the Department of Health and Human Services an Office of the National Coordinator for Health Information Technology (referred to in this section as the “Office”). The Office shall be headed by a National Coordinator who shall be appointed by the Secretary and shall report directly to the Secretary.

**(b) Purpose**

The National Coordinator shall perform the duties under subsection (c) in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information and that--

- (1) ensures that each patient's health information is secure and protected, in accordance with applicable law;
- (2) improves health care quality, reduces medical errors, reduces health disparities, and advances the delivery of patient-centered medical care;
- (3) reduces health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care, and incomplete information;
- (4) provides appropriate information to help guide medical decisions at the time and place of care;
- (5) ensures the inclusion of meaningful public input in such development of such infrastructure;
- (6) improves the coordination of care and information among hospitals, laboratories, physician offices, and other entities through an effective infrastructure for the secure and authorized exchange of health care information;
- (7) improves public health activities and facilitates the early identification and rapid response to public health threats and emergencies, including bioterror events and infectious disease outbreaks;

- (8) facilitates health and clinical research and health care quality;
- (9) promotes early detection, prevention, and management of chronic diseases;
- (10) promotes a more effective marketplace, greater competition, greater systems analysis, increased consumer choice, and improved outcomes in health care services; and
- (11) improves efforts to reduce health disparities.

**(c) Duties of the National Coordinator**

**(1) Standards**

The National Coordinator shall--

- (A) review and determine whether to endorse each standard, implementation specification, and certification criterion for the electronic exchange and use of health information that is recommended by the HIT Advisory Committee under [section 300jj-12](#) of this title for purposes of adoption under [section 300jj-14](#) of this title;
- (B) make such determinations under subparagraph (A), and report to the Secretary such determinations, not later than 45 days after the date the recommendation is received by the Coordinator; and
- (C) review Federal health information technology investments to ensure that Federal health information technology programs are meeting the objectives of the strategic plan published under paragraph (3).

**(2) HIT policy coordination**

**(A) In general**

The National Coordinator shall coordinate health information technology policy and programs of the Department with those of other relevant executive branch agencies with a goal of avoiding duplication of efforts and of helping to ensure that each agency undertakes health information technology activities primarily within the areas of its greatest expertise and technical capability and in a manner towards a coordinated national goal.

**(B) HIT Advisory Committee**

The National Coordinator shall be a leading member in the establishment and operations of the HIT Advisory Committee and shall serve as a liaison between that Committee and the Federal Government.

### **(3) Strategic plan**

#### **(A) In general**

The National Coordinator shall, in consultation with other appropriate Federal agencies (including the National Institute of Standards and Technology), update the Federal Health IT Strategic Plan (developed as of June 3, 2008) to include specific objectives, milestones, and metrics with respect to the following:

- (i)** The electronic exchange and use of health information and the enterprise integration of such information.
- (ii)** The utilization of an electronic health record for each person in the United States by 2014.
- (iii)** The incorporation of privacy and security protections for the electronic exchange of an individual's individually identifiable health information.
- (iv)** Ensuring security methods to ensure appropriate authorization and electronic authentication of health information and specifying technologies or methodologies for rendering health information unusable, unreadable, or indecipherable.
- (v)** Specifying a framework for coordination and flow of recommendations and policies under this part among the Secretary, the National Coordinator, the HIT Advisory Committee, and other health information exchanges and other relevant entities.
- (vi)** Methods to foster the public understanding of health information technology.
- (vii)** Strategies to enhance the use of health information technology in improving the quality of health care, reducing medical errors, reducing health disparities, improving public health, increasing prevention and coordination with community resources, and improving the continuity of care among health care settings.
- (viii)** Specific plans for ensuring that populations with unique needs, such as children, are appropriately addressed in the technology design, as appropriate, which may include technology that automates enrollment and retention for eligible individuals.

#### **(B) Collaboration**

The strategic plan shall be updated through collaboration of public and private entities.

#### **(C) Measurable outcome goals**

The strategic plan update shall include measurable outcome goals.

**(D) Publication**

The National Coordinator shall republish the strategic plan, including all updates.

**(4) Website**

The National Coordinator shall maintain and frequently update an Internet website on which there is posted information on the work, schedules, reports, recommendations, and other information to ensure transparency in promotion of a nationwide health information technology infrastructure.

**(5) Certification**

**(A) In general**

The National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this part. Such program shall include, as appropriate, testing of the technology in accordance with [section 17911\(b\)](#) of this title.

**(B) Certification criteria described**

In this subchapter, the term “certification criteria” means, with respect to standards and implementation specifications for health information technology, criteria to establish that the technology meets such standards and implementation specifications.

**(C) Health information technology for medical specialties and sites of service**

**(i) In general**

The National Coordinator shall encourage, keep, or recognize, through existing authorities, the voluntary certification of health information technology under the program developed under subparagraph (A) for use in medical specialties and sites of service for which no such technology is available or where more technological advancement or integration is needed.

**(ii) Specific medical specialties**

The Secretary shall accept public comment on specific medical specialties and sites of service, in addition to those described in clause (i), for the purpose of selecting additional specialties and sites of service as necessary.

**(iii) Health information technology for pediatrics**

Not later than 18 months after December 13, 2016, the Secretary, in consultation with relevant stakeholders, shall make recommendations for the voluntary certification of health information technology for use by pediatric health providers to

support the health care of children. Not later than 2 years after December 13, 2016, the Secretary shall adopt certification criteria under [section 300jj-14](#) of this title to support the voluntary certification of health information technology for use by pediatric health providers to support the health care of children.

**(D) Conditions of certification**

Not later than 1 year after December 13, 2016, the Secretary, through notice and comment rulemaking, shall require, as a condition of certification and maintenance of certification for programs maintained or recognized under this paragraph, consistent with other conditions and requirements under this subchapter, that the health information technology developer or entity--

(i) does not take any action that constitutes information blocking as defined in [section 300jj-52\(a\)](#) of this title;

(ii) provides assurances satisfactory to the Secretary that such developer or entity, unless for legitimate purposes specified by the Secretary, will not take any action described in clause (i) or any other action that may inhibit the appropriate exchange, access, and use of electronic health information;

(iii) does not prohibit or restrict communication regarding--

(I) the usability of the health information technology;

(II) the interoperability of the health information technology;

(III) the security of the health information technology;

(IV) relevant information regarding users' experiences when using the health information technology;

(V) the business practices of developers of health information technology related to exchanging electronic health information; and

(VI) the manner in which a user of the health information technology has used such technology;

(iv) has published application programming interfaces and allows health information from such technology to be accessed, exchanged, and used without special effort through the use of application programming interfaces or successor technology or standards, as provided for under applicable law, including providing access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws;

(v) has successfully tested the real world use of the technology for interoperability (as defined in [section 300jj](#) of this title) in the type of setting in which such technology would be marketed;

(vi) provides to the Secretary an attestation that the developer or entity--

(I) has not engaged in any of the conduct described in clause (i);

(II) has provided assurances satisfactory to the Secretary in accordance with clause (ii);

(III) does not prohibit or restrict communication as described in clause (iii);

(IV) has published information in accordance with clause (iv);

(V) ensures that its technology allows for health information to be exchanged, accessed, and used, in the manner described in clause (iv); and

(VI) has undertaken real world testing as described in clause (v); and

(vii) submits reporting criteria in accordance with [section 300jj-19a\(b\)](#) of this title.

**(E) Compliance with conditions of certification**

The Secretary may encourage compliance with the conditions of certification described in subparagraph (D) and take action to discourage noncompliance, as appropriate.

**(6) Reports and publications**

**(A) Report on additional funding or authority needed**

Not later than 12 months after February 17, 2009, the National Coordinator shall submit to the appropriate committees of jurisdiction of the House of Representatives and the Senate a report on any additional funding or authority the Coordinator or the HIT Policy Committee or HIT Standards Committee requires to evaluate and develop standards, implementation specifications, and certification criteria, or to achieve full participation of stakeholders in the adoption of a nationwide health information technology infrastructure that allows for the electronic use and exchange of health information.

**(B) Implementation report**

The National Coordinator shall prepare a report that identifies lessons learned from major public and private health care systems in their implementation of health information technology, including information on whether the technologies and practices developed by such systems may be applicable to and usable in whole or in part by other health care providers.

**(C) Assessment of impact of HIT on communities with health disparities and uninsured, underinsured, and medically underserved areas**

The National Coordinator shall assess and publish the impact of health information technology in communities with health disparities and in areas with a high proportion of individuals who are uninsured, underinsured, and medically underserved individuals (including urban and rural areas) and identify practices to increase the adoption of such technology by health care providers in such communities, and the use of health information technology to reduce and better manage chronic diseases.

**(D) Evaluation of benefits and costs of the electronic use and exchange of health information**

The National Coordinator shall evaluate and publish evidence on the benefits and costs of the electronic use and exchange of health information and assess to whom these benefits and costs accrue.

**(E) Resource requirements**

The National Coordinator shall estimate and publish resources required annually to reach the goal of utilization of an electronic health record for each person in the United States by 2014, including--

- (i) the required level of Federal funding;
- (ii) expectations for regional, State, and private investment;
- (iii) the expected contributions by volunteers to activities for the utilization of such records; and
- (iv) the resources needed to establish a health information technology workforce sufficient to support this effort (including education programs in medical informatics and health information management).

**(7) Assistance**

The National Coordinator may provide financial assistance to consumer advocacy groups and not-for-profit entities that work in the public interest for purposes of defraying the cost to such groups and entities to participate under, whether in whole or in part, the National Technology Transfer Act of 1995 (15 U.S.C. 272 note).

**(8) Governance for nationwide health information network**

The National Coordinator shall establish a governance mechanism for the nationwide health information network.

**(9) Support for interoperable networks exchange**

**(A) In general**

The National Coordinator shall, in collaboration with the National Institute of Standards and Technology and other relevant agencies within the Department of Health and Human Services, for the purpose of ensuring full network-to-network



exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally. Such convention may occur at a frequency determined appropriate by the Secretary.

**(B) Establishing a trusted exchange framework**

**(i) In general**

Not later than 6 months after December 13, 2016, the National Coordinator shall convene appropriate public and private stakeholders to develop or support a trusted exchange framework for trust policies and practices and for a common agreement for exchange between health information networks. The common agreement may include--

**(I)** a common method for authenticating trusted health information network participants;

**(II)** a common set of rules for trusted exchange;

**(III)** organizational and operational policies to enable the exchange of health information among networks, including minimum conditions for such exchange to occur; and

**(IV)** a process for filing and adjudicating noncompliance with the terms of the common agreement.

**(ii) Technical assistance**

The National Coordinator, in collaboration with the National Institute of Standards and Technology, shall provide technical assistance on how to implement the trusted exchange framework and common agreement under this paragraph.

**(iii) Pilot testing**

The National Coordinator, in consultation with the National Institute of Standards and Technology, shall provide for the pilot testing of the trusted exchange framework and common agreement established or supported under this subsection (as authorized under [section 17911](#) of this title). The National Coordinator, in consultation with the National Institute of Standards and Technology, may delegate pilot testing activities under this clause to independent entities with appropriate expertise.

**(C) Publication of a trusted exchange framework and common agreement**

Not later than 1 year after convening stakeholders under subparagraph (A), the National Coordinator shall publish on its public Internet website, and in the Federal register,<sup>1</sup> the trusted exchange framework and common agreement developed or supported under subparagraph (B). Such trusted exchange framework and common agreement shall be published in a manner that protects proprietary and security information, including trade secrets and any other protected intellectual property.

**(D) Directory of participating health information networks**

**(i) In general**

Not later than 2 years after convening stakeholders under subparagraph (A), and annually thereafter, the National Coordinator shall publish on its public Internet website a list of the health information networks that have adopted the common agreement and are capable of trusted exchange pursuant to the common agreement developed or supported under paragraph<sup>2</sup> (B).

**(ii) Process**

The Secretary shall, through notice and comment rulemaking, establish a process for health information networks that voluntarily elect to adopt the trusted exchange framework and common agreement to attest to such adoption of the framework and agreement.

**(E) Application of the trusted exchange framework and common agreement**

As appropriate, Federal agencies contracting or entering into agreements with health information exchange networks may require that as each such network upgrades health information technology or trust and operational practices, such network may adopt, where available, the trusted exchange framework and common agreement published under subparagraph (C).

**(F) Rule of construction**

**(i) General adoption**

Nothing in this paragraph shall be construed to require a health information network to adopt the trusted exchange framework or common agreement.

**(ii) Adoption when exchange of information is within network**

Nothing in this paragraph shall be construed to require a health information network to adopt the trusted exchange framework or common agreement for the exchange of electronic health information between participants of the same network.

**(iii) Existing frameworks and agreements**

The trusted exchange framework and common agreement published under subparagraph (C) shall take into account existing trusted exchange frameworks and agreements used by health information networks to avoid the disruption of existing exchanges between participants of health information networks.

**(iv) Application by Federal agencies**

Notwithstanding clauses (i), (ii), and (iii), Federal agencies may require the adoption of the trusted exchange framework and common agreement published under subparagraph (C) for health information exchanges contracting with or entering into agreements pursuant to subparagraph (E).

**(v) Consideration of ongoing work**

In carrying out this paragraph, the Secretary shall ensure the consideration of activities carried out by public and private organizations related to exchange between health information exchanges to avoid duplication of efforts.

**(d) Detail of Federal employees**

**(1) In general**

Upon the request of the National Coordinator, the head of any Federal agency is authorized to detail, with or without reimbursement from the Office, any of the personnel of such agency to the Office to assist it in carrying out its duties under this section.

**(2) Effect of detail**

Any detail of personnel under paragraph (1) shall--

(A) not interrupt or otherwise affect the civil service status or privileges of the Federal employee; and

(B) be in addition to any other staff of the Department employed by the National Coordinator.

**(3) Acceptance of detailees**

Notwithstanding any other provision of law, the Office may accept detailed personnel from other Federal agencies without regard to whether the agency described under paragraph (1) is reimbursed.

**(e) Chief Privacy Officer of the Office of the National Coordinator**

Not later than 12 months after February 17, 2009, the Secretary shall appoint a Chief Privacy Officer of the Office of the National Coordinator, whose duty it shall be to advise the National Coordinator on privacy, security, and data stewardship of electronic health information and to coordinate with other Federal agencies (and similar privacy officers in such agencies), with State and regional efforts, and with foreign countries with regard to the privacy, security, and data stewardship of electronic individually identifiable health information.

**CREDIT(S)**

(July 1, 1944, c. 373, Title XXX, § 3001, as added [Pub.L. 111-5](#), Div. A, Title XIII, § 13101, Feb. 17, 2009, 123 Stat. 230; amended [Pub.L. 114-255](#), Div. A, Title IV, §§ 4001(b), 4002(a), 4003(b), (e)(2)(A)(i), (ii), (C), Dec. 13, 2016, 130 Stat. 1158, 1159, 1165, 1174.)

Notes of Decisions (3)

### Footnotes

<sup>1</sup> So in original. Probably should be “Register,”.

<sup>2</sup> So in original. Probably should be “subparagraph”.

42 U.S.C.A. § 300jj-11, 42 USCA § 300jj-11

Current through P.L. 118-7. Some statute sections may be more current, see credits for details.

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